

**Notice of Allowability**

Application No.

09/777,091

Examiner

JAVIER G. BLANCO

Applicant(s)

PAVCNIK ET AL.

Art Unit

3774

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Response/Amendment filed on October 31, 2007 and January 15, 2008.
2. ☒ The allowed claim(s) is/are 1, 2, 4-13, 16, 55--64, 66, and 67.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |   |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application   |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>6/24/2008</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date ____     | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance                          |
|  | 9. <input type="checkbox"/> Other ____.   |

/Javier G. Blanco/  
Examiner, Art Unit 3774

### **DETAILED ACTION**

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 31, 2007 has been entered.

### **EXAMINER'S AMENDMENT**

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Attorney Kenneth A. Gandy on June 24, 2008.

The application has been amended as follows:

**Claim 1** (Currently Amended) An implantable valve for a bodily passage of tubular shape, comprising:

a self-expanding support frame having a first end and a second end, said support frame configured for expansion to conform to a wall of the bodily passage, said support frame having a ~~plurality of~~ only two, three or four bends occurring at each end of said first end and said second

Art Unit: 3738

end of said support frame, said ~~plurality of~~ bends configured to provide outward radial force for expansion of said self-expanding frame to anchor the implantable valve to the wall of the bodily passage, said support frame when expanded providing a plurality of side elements each defining a path extending at least partially longitudinally along the wall and at least partially circumferentially around the wall,

a ~~plurality of~~ only two, three or four leaflets, each leaflet ~~thereof~~ having a body extending from a wall-engaging outer edge to an inner edge proximate a corresponding inner edge of at least one other leaflet of the plurality of leaflets,

the inner edges of said ~~plurality of~~ leaflets cooperable to define an opening therebetween to permit fluid flow in a first direction along the bodily passage, and further cooperable to engage each other sufficiently to restrict fluid flow in a second direction opposing the first direction,

the outer edge of each one of the ~~plurality of~~ leaflets includes an attachment extending along at least selected ones of the side elements such that the outer edge is adapted to resiliently and sealingly engage the wall of the bodily passage along said path, wherein said attachment includes an amount of the outer edge of the leaflet wrapped around a corresponding side element to which the outer edge is attached so as to provide an amount of material from which the leaflet is made occurring on an outer side of said corresponding side element, each leaflet extending along said bodily passage away from the inner edges thereof in said second direction to form a curved structure for trapping fluid against the inner wall of the bodily passage in response to fluid flow in said second direction so as to cause said inner edges of said leaflets to engage one another sufficiently to restrict fluid flow in said second direction; ~~and~~

wherein the implantable valve further includes at least one barb to anchor the implantable valve to the wall of the bodily passage;

wherein the number of leaflets of said implantable valve is equal to the number of bends occurring at each end of the support frame; and

wherein said support frame is adapted to assume a plurality of configurations, a first configuration of the plurality of configurations being a generally flat plane.

**Claim 4** (Currently Amended) The implantable valve of claim 1 wherein the outer edges of the ~~plurality of~~ leaflets include overhanging material, the overhanging material extending beyond the frame to which the plurality of leaflets are attached.

**Claim 6** (Currently Amended) The implantable valve of claim 1 wherein the ~~plurality of leaflets~~ valve includes only two leaflets such that when the frame is substantially flattened, it assumes a diamond shape with the inner edges of the two leaflets defining a slit therebetween.

**Claim 10** (Currently Amended) The implantable valve of claim 1 wherein the ~~plurality of~~ leaflets comprise an extracellular collagen matrix.

**Claim 13** (Currently Amended) The implantable valve of claim 1 wherein the frame is adapted to assume a plurality of configurations, and the plurality of configurations includes a generally flat configuration, whereby the frame in the generally flat configuration is generally diamond-shaped.

Art Unit: 3738

**Claim 16** (Currently Amended) The implantable valve of ~~Claim 15~~ claim 1 wherein the at least one barb is an integral projection extending from the frame.

**Claim 55** (Currently Amended) ~~An~~ A bi-leaflet implantable valve for a bodily passage of tubular shape, comprising:

a support frame having a first end and a second end, said support frame having only two bends at each of said first end and said second end, said support frame configured for expansion to conform to a wall of the bodily passage, said support frame when expanded providing a plurality of side elements each defining a path extending at least partially longitudinally along the wall and at least partially circumferentially around the wall,

~~a plurality of~~ only two leaflets, each leaflet comprising an extracellular collagen matrix material, each leaflet ~~thereof~~ having a body extending from a wall-engaging outer edge to an inner edge proximate a corresponding inner edge of ~~at least one~~ the other leaflet ~~of the plurality of leaflets,~~

the inner edges of said ~~plurality of~~ leaflets cooperable to define an opening therebetween to permit fluid flow in a first direction along the bodily passage, and further cooperable to engage each other sufficiently to restrict fluid flow in a second direction opposing the first direction,

the outer edge of each one of the ~~plurality of~~ leaflets attached along one side element of said plurality of side elements and thereby adapted to directly engage the wall of the bodily passage therearound and provide ingrowth of adjacent native tissue into the extracellular collagen matrix material, wherein the outer edge of each one of the plurality of leaflets is

Art Unit: 3738

wrapped around a corresponding side element to which the outer edge is attached so as to provide an amount of material from which the leaflet is made occurring on an outer side of said corresponding side element; and

wherein the implantable valve includes at least one barb to anchor the implantable valve to the wall of the bodily passage.

**Claim 58** (Currently Amended) An implantable valve for a bodily passage of tubular shape, comprising:

a frame that includes a first end and a second end and a plurality of legs, each of the legs originating from a pair of bends located about ~~a~~ the first end of the ~~frame implantable valve~~, and extending in an opposite direction therefrom, each of the plurality of legs terminating at ~~a~~ the second end of the ~~frame implantable valve~~ opposite the first end such that the plurality of legs generally assume a serpentine configuration along the circumference of a bodily passage when situated therein,

a plurality of leaflets, each leaflet comprising a covering that includes one or more flexible materials, the leaflet including a body that comprises a wall-engaging outer edge and an inner edge, the outer edge at least partially attached to, and reinforced by one of the plurality of legs, the outer edge and the associated leg adapted to sealingly engage the inner wall of the bodily passage, and wherein the outer edge is wrapped around a corresponding leg to which the outer edge is attached so as to provide an amount of material from which the leaflet is made occurring on an outer side of said corresponding leg;

Art Unit: 3738

wherein the body of the leaflet extends inward from the wall of the bodily passage and extending toward the first end of the implantable valve where it terminates at the inner edge, the body and inner edge traversing the lumen of the bodily passage when situated therein and being configured such that the leaflet is cooperable with at least one other leaflet to define an opening that permits positive flow of fluid therethrough in a first direction, while the plurality of leaflets are further adapted to trap between the leaflets and the inner wall of the bodily passage fluid flowing in a second direction opposite the first direction and seal against one another to restrict fluid flow in said second direction;

wherein the frame is adapted to assume a plurality of configurations, a first configuration of the plurality of configurations being a generally flat plane; and

wherein the implantable valve includes at least one barb to anchor the implantable valve to the wall of the bodily passage; and

wherein the number of leaflets of said implantable valve is equal to the number of bends occurring at each end of the frame.

**Claim 60** (Currently Amended) A bi-leaflet valve prosthesis for implantation in a blood vessel, comprising:

a support frame including a plurality of bends and interconnected sides, the support frame having a first configuration for intravascular delivery into the blood vessel and a second configuration for implantation therein; the support frame having a first end and a second end, and the support frame having only two said bends occurring at each of said first end and second end;

only two ~~a pair of~~ opposing leaflets, each leaflet having an inner edge and an outer edge;

wherein the inner edges of the opposing leaflets are cooperable with one another to permit blood flow in a first direction within the vessel ~~vein~~, while restricting blood flow in a second direction opposite the first direction; and

wherein the outer edge of each of the ~~plurality of~~ leaflets is attached to at least one of the plurality of interconnected side elements such that the plurality of outer edges engage ~~the~~ walls of the bodily passage and collectively form a seal thereagainst along a pathway defined by the plurality of interconnected side elements;

wherein the outer edge of each of the ~~plurality of~~ leaflets includes an amount wrapped around a corresponding side element to which the outer edge is attached so as to provide an amount of material from which the leaflet is made occurring on an outer side of said side element; and

wherein the prosthesis includes at least one barb to anchor the prosthesis to a wall of the bodily passage.

**Claim 61** (Currently Amended) The valve prosthesis of claim 55 wherein the ~~plurality of~~ leaflets comprise a bioremodelable material.

**Claim 62** (Currently Amended) The valve prosthesis of claim 61 wherein the ~~plurality of~~ leaflets comprise an extracellular collagen matrix.

**Claim 63** (Currently Amended) The valve prosthesis of claim 60, wherein the leaflets form a curved structure for trapping fluid between the ~~plurality of~~ leaflets and the inner wall of the



Art Unit: 3738

blood vessel in response to fluid flow in the second direction so as to restrict the flow passing through the valve prosthesis in the second direction.

**Claim 64** (Currently Amended) The valve prosthesis of claims 60, wherein the ~~plurality of bends~~ two bends occurring at the first end of the frame include ~~at least~~ a first bend and a second bend ~~located about the first end of the prosthesis~~, the first bend and the second bend interconnecting two of the plurality of interconnected sides, each of the two interconnected sides extending at least partially longitudinally from the first bend and the second bend toward the second end of the ~~frame prosthesis~~; and wherein the inner edges of the ~~plurality of~~ leaflets each include a first end and a second end, each of the first and second ends being carried about at least one of the first bend and the second bend.

**Claim 65** has been cancelled.

**Claim 66** (Currently Amended) A bi-leaflet vascular valve prosthesis, comprising:

a support frame including a first end and a second end and a plurality of bends and interconnected side elements, the support frame having a first configuration for intravascular delivery and a second configuration for implantation in a vascular vessel;

~~the plurality of~~ only two bends occurring at each of said first end and said second end of said support frame, said bends including a first bend and a second bend at said first end of said support frame, wherein the first bend and the second bend are adapted to be positioned opposite one another when the support frame is in the second configuration;

Art Unit: 3738

only two leaflets, said two leaflets including a first leaflet and a second leaflet providing a bi-leaflet valve configuration having a valve orifice extending in a direction between the first bend and the second bend;

the first leaflet having a first outer edge portion attached extending along a side element connected to said first bend, and a second outer edge portion attached extending along a side element connected to the second bend; ~~and~~

the second leaflet having a first outer edge portion attached extending along a side element connected to the first bend and a second outer edge portion attached extending along a side element connected to the second bend;

wherein each of said outer edge portions is wrapped around a corresponding side element to which the outer edge portion is attached so as to provide an amount of material occurring on an outer side of said corresponding leg; and

wherein said prosthesis includes at least one barb to anchor the prosthesis to a vascular vessel.

The following is an examiner's statement of reasons for allowance: the Prior Art does not disclose or suggest an implantable valve comprising the combination of structural and functional limitations as disclosed in independent claims 1, 55, 58, 60, and 66. Mainly, a self-expanding support frame having a first end and a second end, said support frame having only two, three or four bends occurring at each end of said first end and said second end of said support frame, only two, three or four leaflets, an amount of the outer edge of the leaflet wrapped around a corresponding side element to which the outer edge is attached so as to provide an amount of

Art Unit: 3738

material from which the leaflet is made occurring on an outer side of said corresponding side element, and wherein the number of leaflets of said implantable valve is equal to the number of bends occurring at each end of the support frame.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:00 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on **(571)272-4749**. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

Art Unit: 3738

system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Javier G. Blanco/

Examiner, Art Unit 3774

/Dave Willse/

Primary Examiner, Art Unit 3738